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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,018	03/15/2004	William V. Judy	JUDY3	6808
1444 7590 04/30/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER NATNITHITHADHA, NAVIN	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 04/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,018

Applicant(s)

JUDY, WILLIAM V.

Examiner

Navin Natnithithadha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20040719</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 19 July 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language (i.e. DE 2,620,285, Siemens AG). It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

2. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Objections

3. Claims 1 and 9 are objected to because of the following informalities:

It is not clear whether the limitation "in particular a human being" is part of the claimed invention.

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Appropriate correction is required.

4. Claims 2-4, 7, and 8 is objected to because of the following informalities:

It is not clear whether the limitations "processing means are designed to..." and "processing means are further designed to..." are directed to more than one processing means, and whether the processing means actually does the designated functions. The examiner suggests amending the limitation to - - processing means - -.

Appropriate correction is required.

Examiner's Comment

5. In order to clearly define the structure of the apparatus in claim 1, the Examiner suggests the following amendments:

- a) in line 4, amend "comprising" to - - comprising: - -;
- b) in line 6, amend "which" to - - wherein - -;
- c) in line 7, amend "comprises" to - - comprises: - -;
- d) in line 9, amend "measuring means , and further comprising" to - - measuring means; and - -.

In addition, the Examiner suggests using indentations to clearly define the structure of the apparatus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Noren et al, US 5,417,715 A ("Noren").

Claims 1-3: Noren teaches a device 1 for determining at least the blood flow through at least a selected half of a coronary artery system of a beating heart 4 of a mammal (see figs. 1 and 2) during a beat of said heart, comprising:

a bioimpedance measuring device (impedance meter) 11 for measuring an impedance signal Z that depends on said blood flow through at least said selected half of said coronary artery system, wherein the bioimpedance measuring device 11 comprises a current source (pulse generator) 8, electrodes (electrodes and electrode conductor) 2, 3, 5, and 6 and measuring means (bandpass filter) 18; and

processing means (control unit) 23 which are connected to said measuring means 18, for processing of at least a value of said impedance signal Z (measurement signal or impedance signal Z, see col. 5, ll. 31-35, and col. 6, l. 32), and for determining a first time-derivative dZ/dt of said impedance signal Z (differentiated in a differentiator 19, see col. 5, ll. 37-40), wherein said processing means 23 further comprise means for separating from said first time-derivative dZ/dt a peak signal PS corresponding to said selected half of said coronary artery system (peak value detector, see col. 42-44), which peak signal PS lies within a time interval between the beginning of diastole of said heartbeat and the end of a second peak signal PS2 of said first time-derivative dZ/dt which occurs second after said beginning of diastole (see col. 5, ll. 40-47, and col. 6, ll.

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34-47), and wherein said processing means 23 are designed to determine said blood flow from said peak signal PS (see col. 10, ll. 1-3), wherein said processing means determines said blood flow through said selected half of said coronary artery system from a first peak signal PS1 or second peak signal PS2 which occurs first or second after said beginning of diastole of said heart beat (see col. 5, ll. 40-41), in the case that said selected half of said coronary artery system is the left or right half of said coronary artery system of said heart (generally stated as "ventricle", which implies left or right ventricle, see col. 5, ll. 32-35).

Claims 9-11: Because claims 9-11 are not distinct from claims 1-3, the claimed method is also anticipated by Noren for the same reasons above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4-8 and 12-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noren, as applied to claim 1 above, and further in view of over Ackmann et al, US 5,178,154 A ("Ackmann").

Claims 4-8: Noren does not teach determining the total coronary artery flow time, the blood flow volume through the selected half of the coronary artery system, and the heart rate, the blood flow volume CAQ per unit time through the selected half of the coronary

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artery system, and the total blood flow volume through the coronary artery system.

However, the determination of these parameters from an impedance signal is well

known in the art. For example, Ackmann discloses the following:

To obtain the cardiac output, the stroke volume representing the amount of blood being ejected during each cardiac cycle first must be computed. Stroke volume can be determined from the following equation disclosed by William G.

Kubicek et al. in U.S. Pat. No. 3,340,867:

$$EV = \rho * (L^2 T / Z_o^2) * (dZ / dt_{max})$$

where SV is the ventricular stroke volume, ρ is the resistivity of blood at the excitation frequency, L is the shortest distance between the inner electrodes, Z_o is the average baseline impedance between the inner electrodes, T is the ventricular ejection time, and dZ / dt_{max} is the magnitude of the first derivative of the thoracic impedance. The cardiac output then is computed by multiplying the stroke volume by the heart rate.

(see col. 1, ll. 28-46, also see Wang et al, US 5,309,917 A, col. 2, ll. 21-36). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Noren to derive these well-known cardiac parameters from the impedance signal and for the purpose of controlling the heart stimulation rate (see Noren, col. 1, ll. 6-15).

Claims 12-17: Because claims 12-17 are not distinct from claims 4-8, the claimed method is also anticipated by Noren in view of Ackmann for the same reasons above.


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Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Navin Natnithithadha
Patent Examiner
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